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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,303	11/06/2003	Arnold R. Leiboff	461.1008	8007
22846	7590	12/05/2008		
BRIAN ROFFE, ESQ. 11 SUNRISE PLAZA, SUITE 303 VALLEY STREAM, NY 11580-6111			EXAMINER HALL, DEANNA K	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 12/05/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/702,303

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

DEANNA K. HALL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) 1-6, 15-28 and 30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 7-14, 29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on September 8, 2008.
2. In the reply, the applicant elected group II, claims 7-14 and 29. Claims 1-30 are pending in the application.

Claim Objections

3. Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 14 depends on independent claim 7; however, claim 7 requires directing fluid through the passage while the irrigation tube is situated over or along the guidewire whereas claim 14 requires withdrawing the guidewire from the irrigation tube before fluid is directed through the passage.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7-11, 14 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanson et al. (US 5,709,874) ("Hanson").

Hanson discloses a method for irrigating a body cavity C5 L46-49; comprising:

Pushing a guidewire 28 having a bulbous enlargement 30 at a distal end into the body cavity; then sliding an irrigating tube 12 over or along the guidewire, the irrigating tube having a distal end 19, a passage 20 and an opening 24 at or near the distal end which communicates with the passage; then directing fluid 25 through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire. See Figs. 2, 9.

The body cavity of Hanson can be the colon whereby the guidewire would be pushed through the anal sphincter and rectum into the colon C4 L11-25.

The bulbous enlargement 30 has a smooth outer arcuate surface Fig. 2 such that the body cavity is not perforated.

The guidewire 28 is situated in the passage 20 defined by the irrigating tube 12 and the irrigating tube slides over the guidewire, the fluid 25 being directed in the passage over the guidewire, see Figs. 2, 9.

The guidewire is guided through the body cavity by manipulating the bulbous enlargement C6 L33-37.

According to claim 14, the guidewire can also be withdrawn from the irrigating tube before fluid is directed through the passage defined by the irrigating tube C13 L19-39.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson in view of Majlessi (US 4,842,583).

Hanson discloses the invention as substantially claimed (see above). However, Hanson does not directly disclose the size of the bulbous enlargement to have a diameter of about 0.25in to about 0.75in. Hanson does disclose that the length and diameter of the tube 12 with vary depending on the body conduit C4 L59-65. Further, all the figures of Hanson show the guidewire 28 with its bulbous enlargement 30 being sized to fit within the tube 12. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the size of the tube 12 and thus also the size of the guidewire and bulbous enlargement to correspond to a size appropriate for insertion into the colon. A bulbous enlargement with a size of about 0.25in to about 0.75in would be an appropriate size for insertion into the colon. This sized bulbous enlargement is also taught by Majlessi and guiding the guidewire through the body cavity by manipulating (grasping) the bulbous enlargement and pulling the guidewire outward from the body cavity to compress and shorten the distance between an entrance to the body cavity and a treatment site C3 L54-61. It would be obvious to combining Hanson and Majlessi because Majlessi discloses a

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guidewire and irrigation tube in one piece Hanson is an obvious variant in that in Hanson the guidewire and irrigation tube are separate pieces. It has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/

Examiner, Art Unit 3767

12/3/08

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767